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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHENIQUA BIVINS, **Plaintiff,** **v.** **NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA GMBH, and NOVARTIS AG,** **Defendants.**	**Civil Action No.:** *Document electronically filed.* **ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION TO THE PLAINTIFF'S COMPLAINT**

Defendant Novartis Pharmaceuticals Corporation ("NPC") responds to Plaintiff's Complaint ("Complaint") as follows:

BACKGROUND

1. NPC denies any and all wrongful conduct as alleged. NPC further denies that Plaintiff suffered any damage or harm as a proximate result of any alleged wrongful conduct by NPC.

2. NPC denies each and every allegation contained in paragraph 2.

JURISDICTION AND VENUE

3. NPC admits that the amount in controversy exceeds $75,000.

4. NPC admits that it is and has been at all relevant times a corporation incorporated under the laws of the State of Delaware with its principal place of business in the State of New Jersey. The remaining allegations in paragraph 4 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits for itself only that jurisdiction over NPC exists in the United States District Court for the District of New Jersey.

5. NPC admits that the Plaintiff has brought this lawsuit under the statute(s) identified in paragraph 5. NPC denies that it violated any statute or legal duty and further denies that it is liable to Plaintiff for any relief sought in paragraph 5.

PARTIES

6. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 6.

7. NPC admits that it is and has been at all relevant times a corporation incorporated under the laws of the State of Delaware with its principal place of business in the State of New Jersey.

8. NPC denies that it is a subsidiary or alter-ego of Novartis Pharma GmbH. The remaining allegations in paragraph 8 relate to parties other than NPC and assert legal conclusions to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 8.

9. Paragraph 9 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 9.

10. NPC denies that it is a subsidiary or alter-ego of Novartis AG. The remaining allegations in paragraph 10 relate to parties other than NPC and assert legal conclusions to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 10.

11. Paragraph 11 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. NPC admits that Novartis AG indirectly owns a 100% interest in NPC and that Novartis AG owns the patent on pimecrolimus and the trademark for the word "Elidel" in the United States. To the extent that a further response is required, NPC denies the remaining allegations in paragraph 11.

12. Paragraph 12 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 12.

13. NPC admits that the Plaintiff uses the term "Novartis Defendants" collectively to refer to several defendants. NPC denies any legal relationship arising from the collective reference. By way of further answer, NPC is a separate corporation and should be referred to individually to maintain clarity in the pleadings. NPC is answering the Complaint solely on its own behalf and is not acting in any capacity for any other defendant.

14. Paragraph 14 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 14 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has

marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 14.

15. Paragraph 15 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 15.

FACTUAL BACKGROUND

16. NPC admits that United States Patent number 5,912,238 is for pimecrolimus and is owned by Novartis AG. The remaining allegations in paragraph 16 are directed toward other defendants and NPC lacks sufficient knowledge or information to form a belief as to the truth of those allegations, which are therefore denied.

17. NPC admits that pimecrolimus is a macrolide lactone and can be derived from ascomycin, and that it was developed under the name SDZ ASM 981. The remaining allegations in paragraph 17 relate to parties other than NPC to which no response is required. To the extent that a further response is required, NPC states, upon information and belief, that in 1996 Ciba-Geigy and Sandoz merged into Novartis AG, and NPC denies the remaining allegations in paragraph 17.

18. NPC admits that pimecrolimus and tacrolimus bind to the macrophilin-12 receptor, but with different affinities. Pimecrolimus and tacrolimus can be calcineurin inhibitors because the drug macrophilin complex can block the calcium-induced phosphatase action of calcineurin. Blocking the action of calcineurin prevents the release of inflammatory cytokines from T cells and also inhibits proliferation of activated T cells. NPC denies the remaining allegations in paragraph 18.

19. NPC admits that the United States Adopted Names Council has assigned the names of "pimecrolimus" and "tacrolimus." The remaining allegations in paragraph 19 concern the intent and mental impressions of parties other than NPC to which no response is required. To the extent that a further response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 19, which are therefore denied.

20. Paragraph 20 contains allegations regarding other parties to which no response is required. To the extent the allegations relate to NPC, NPC admits that the FDA approved the pimecrolimus cream Elidel® as safe and effective for the following indication on December 13, 2001, as set forth in the package insert which was approved by the FDA on that date and provides:

> Elidel (pimecrolimus) Cream 1% is indicated for short-term and intermittent long-term therapy in the treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative conventional therapies. (See **DOSAGE AND ADMINISTRATION** Section)

To the extent any further response is required, NPC denies the allegations in Paragraph 20.

21. Denied. Eczema is a common name for atopic dermatitis.

22. NPC admits that at least one calcineurin inhibitor was approved as indicated by the FDA to prevent organ rejection in transplant patients prior to December 13, 2001. NPC denies the remaining allegations in paragraph 22.

23. NPC denies the allegations in paragraph 23. By way of further answer, FDA approved pimecrolimus as safe and effective on December 13, 2001.

24. NPC denies the allegations in paragraph 24. By way of further answer, FDA approved pimecrolimus as safe and effective on December 13, 2001, subject to the following commitment (among others):

> We agree to conduct a registry study of pediatric patients (aged 2-17), with emphasis on the younger ages) with atopic dermatitis followed through adulthood for those who have long-term intermittent treatment with Elidel (pimecrolimus) 1% cream to assess the risk of developing systemic malignancies.

25. NPC admits that on October 30, 2003, a meeting open to the public of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee was held to discuss how to approach long-term monitoring for cancer occurrence among patients treated for atopic dermatitis with pimecrolimus and tacrolimus. NPC denies the remaining allegations in paragraph 25.

26. NPC denies the allegations in paragraph 26.

27. NPC admits that the "Summary Minutes" for the October 30, 2003, subcommittee meeting stated in part: "For children under 2, because of immune system development issues and lack of understanding regarding the development of other systems in the very young a Box warning was recommended." NPC further admits that the FDA did not choose to change the package insert to include a black box warning at that time. To the extent any further response is required, NPC denies the remaining allegations in paragraph 27.

28. NPC admits that anecdotal reports of malignancies in patients using pimecrolimus were reported to the FDA after October 2003. NPC denies that such reports were caused by pimecrolimus. NPC denies the remaining allegations in paragraph 28.

29. NPC admits that pimecrolimus was discussed at a meeting of the Pediatric Advisory Committee on February 15, 2005. NPC denies the remaining allegations in paragraph 29.

30. Paragraph 30 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, NPC admits that on March 10, 2005, the FDA issued a Public Health Advisory "about a potential cancer risk from use of Elidel® (pimecrolimus) and Protopic® (tacrolimus)" in which it stated that "FDA will require labeling changes for Elidel and Protopic, including the placement of a boxed warning about the potential cancer risk." NPC denies the remaining allegations in paragraph 30.

31. Paragraph 31 contains allegations regarding parties other than NPC to which no response is required. To the extent the allegations relate to NPC, NPC admits that FDA and NPC agreed to appropriate language for the black box warning in January 2006, and that this change was then made to the label. NPC denies the remaining allegations in paragraph 31.

THE NOVARTIS DEFENDANTS

32. Paragraph 32 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel®, in the United States, for the approved indications listed on the label for Elidel®. NPC denies the remaining allegations contained in paragraph 32.

33. Paragraph 33 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it received approval from the FDA on December 13, 2001 to market Elidel® for certain approved indications and that the terms of the FDA's approval, set forth in writing in their approval letter, speak for themselves. NPC denies the remaining allegations contained in paragraph 33.

34. Paragraph 34 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and

markets Elidel® for certain approved indications. NPC denies the remaining allegations contained in paragraph 34.

35. Paragraph 35 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and markets Elidel® for certain approved indications. NPC denies the remaining allegations contained in paragraph 35.

36. Paragraph 36 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits the allegations as they relate to NPC only.

37. NPC denies the allegations contained in paragraph 37.

38. Paragraph 38 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it distributes and markets Elidel® for certain approved indications using ordinary marketing practices. NPC denies the remaining allegations contained in paragraph 38.

39. Paragraph 39 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that the number of prescriptions for Elidel® through 2005 totaled in the millions. NPC denies the remaining allegations contained in paragraph 39.

40. NPC admits that it received approval from FDA on December 13, 2001 to market Elidel® for certain approved indications and that the package inserts and product labeling for Elidel® speak for themselves. NPC denies the remaining allegations contained in paragraph 40.

41. NPC admits that it received approval from FDA on December 13, 2001 to market Elidel® for certain approved indications and that the package inserts and product labeling for Elidel® speak for themselves. NPC denies the remaining allegations contained in paragraph 41.

42. Paragraph 42 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, the allegations in paragraph 42 are denied.

43. Paragraph 43 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, the allegations in paragraph 43 are denied.

44. Paragraph 44 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 44 are denied.

45. Paragraph 45 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, the allegations in paragraph 45 are denied.

46. Paragraph 46 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 46 are denied.

47. Paragraph 47 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 47 are denied.

48. Paragraph 48 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 48 are denied.

49. Paragraph 49 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 49 are denied.

50. Paragraph 50 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 50 are denied.

51. Paragraph 51 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 51 are denied.

52. Paragraph 52 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 52 are denied.

53. Paragraph 53 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 53 are denied.

54. Paragraph 54 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 54 are denied.

FACTUAL ALLEGATIONS – SHENIQUA BIVINS'S CASE

55. Paragraph 55 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or her treating physicians reviewed prior to April 2003, and NPC denies the remaining allegations in paragraph 55.

56. Paragraph 56 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or her treating physicians reviewed and NPC denies the remaining allegations in paragraph 56.

57. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 57. To the extent that a response is required, NPC denies the allegations in paragraph 57.

58. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations that Plaintiff was diagnosed with a form of cancer, more specifically T-cell lymphoma. NPC denies the remaining allegations in paragraph 58.

59. NPC is without sufficient knowledge or information to form a belief regarding what Elidel®-related materials Plaintiff or her treating physicians had at the alleged material times. NPC denies the remaining allegations in paragraph 59.

COUNT I
Products Liability Act – Failure to Warn

60. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

61. Paragraph 61 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 61 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 61.

62. Paragraph 62 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 62 are denied.

63. Paragraph 63 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 63 are denied.

64. Paragraph 64 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 64 are denied.

65. Paragraph 65 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 65 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 65.

66. Paragraph 66 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 66 are denied.

67. Paragraph 67 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 67 are denied.

COUNT II
Products Liability Act – Defective Design

68. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

69. Paragraph 69 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label and been involved in its testing and development. NPC denies the remaining allegations in paragraph 69.

70. NPC denies the allegations contained in paragraph 70.

71. NPC denies the allegations contained in paragraph 71.

72. Paragraph 72 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 72.

73. Paragraph 73 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding how the plaintiff used Elidel®. To the extent that a response is required, NPC denies the allegations in paragraph 73.

74. Paragraph 74 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 74.

75. Paragraph 75 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 75.

76. Paragraph 76 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 76.

COUNT III
Breach of Express Warranty

77. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

78. Paragraph 78 contains allegations regarding parties other than NPC to which no response is required. The remaining allegations in paragraph 78 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it has marketed Elidel® in accordance with its label. NPC denies the remaining allegations in paragraph 78.

79. Paragraph 79 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 79 are denied.

80. Paragraph 80 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 80 are denied.

81. NPC denies the allegations contained in paragraph 81.

82. NPC is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 82. To the extent that a response is required, NPC denies the allegations in paragraph 82.

83. NPC denies the allegations contained in paragraph 83.

84. Paragraph 84 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 84 are denied.

85. Paragraph 85 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 85 are denied.

COUNT IV
Products Liability Act - Breach of Implied Warranty

86. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

87. Paragraph 87 contains legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in paragraph 87.

88. NPC denies the allegations contained in paragraph 88.

89. Paragraph 89 contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC is without sufficient knowledge or information to form a belief regarding how the plaintiff used Elidel®. To the extent that a further response is required, NPC denies the allegations in paragraph 89.

90. NPC denies the allegations contained in paragraph 90.

91. Paragraph 91 contains legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 91 are denied.

92. Paragraph 92 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, the allegations in paragraph 92 are denied.

COUNT V
Punitive Damages Under Common Law and Products Liability Act

93. NPC incorporates by reference its responses to all other paragraphs of the Complaint as if fully set forth herein.

94. NPC denies that it made false representations or actively concealed safety information regarding Elidel® from the medical community and the public, including the plaintiff. The remaining allegations in paragraph 94 relate to parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 94.

95. NPC denies that it knowingly withheld material information from the FDA, the medical community and the public, including the plaintiff. The remaining allegations in paragraph 95 relate to parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the remaining allegations in paragraph 95.

96. Paragraph 96 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 96.

97. Paragraph 97 contains allegations regarding parties other than NPC and legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in paragraph 97.

RELIEF REQUESTED

NPC denies that Plaintiff is entitled to any of the relief requested in the Complaint, including any relief requested in any WHEREFORE clause contained in the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim or cause of action against NPC upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar Plaintiff's claims against NPC in whole or in part.

THIRD AFFIRMATIVE DEFENSE

The doctrine(s) contained in Restatement (Third) of Torts, Product Liability § 6, bar Plaintiff's claims against NPC in whole or in part.

FOURTH AFFIRMATIVE DEFENSE

Applicable statutes of limitation bar Plaintiff's claims in whole or in part.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's misuse, abnormal use, or use without a prescription of the product or failure to follow instructions bars Plaintiff's claims in whole or in part.

SIXTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, then Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the product label and instructions, by the prescribing physicians, or by other persons or entities.

SEVENTH AFFIRMATIVE DEFENSE

Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent Plaintiff did not use Elidel®.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, Plaintiff's claim is barred to the extent Plaintiff used the product without a prescription.

TENTH AFFIRMATIVE DEFENSE

The learned intermediary doctrine bars Plaintiff's claims.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the product at issue, Elidel®, was designed, manufactured, labeled, marketed, and sold with adequate warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or part, because the product at issue, Elidel®, was not defectively designed or manufactured and was not unreasonably dangerous and complied with all applicable government safety standards and/or FDA regulations.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, marketing, modeling, processing and supplying of pharmaceutical products including Elidel®.

FOURTEENTH AFFIRMATIVE DEFENSE

If Plaintiff used a product sold by NPC, then Plaintiff's claims are barred, in whole or in part, because Plaintiff suffered no compensable injury as a result of such use.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff and/or independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical conditions.

SIXTEENTH AFFIRMATIVE DEFENSE

If Plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiff's injuries or damages.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by Elidel®, which is denied, were the result of Plaintiff's own idiosyncratic reactions.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff failed to mitigate, which limits Plaintiff's damages, if any, in whole or in part.

NINETEENTH AFFIRMATIVE DEFENSE

NPC has no legal relationship or privity with Plaintiff and owes no duty to Plaintiff by which liability could be attributed to it.

TWENTIETH AFFIRMATIVE DEFENSE

NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which NPC specifically denies, then Plaintiff failed to give notice of any breach thereof.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are barred because such an award would violate NPC's due process, equal protection and other rights under the United States Constitution, the New Jersey Constitution, the Texas Constitution and/or other applicable constitutions.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are barred because Plaintiff has failed to allege conduct warranting imposition of punitive damages under the United States Constitution, the New Jersey Constitution, the Texas Constitution, and/or other applicable state laws.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred, in whole or in part, by Plaintiff's own contributory/comparative negligence.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff has received from collateral sources.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Elidel®.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claim for punitive damages is preempted, in whole or in part, by applicable federal law.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff is limited in the amount, if any, she may recover for punitive damages under N.J.S.A. § 2A:15-5.9 *et seq.* and/or other applicable state laws.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff is barred from recovering punitive damages under N.J.S.A. § 2A:58C-5(c) and/or other applicable state laws because Elidel® was subject to pre-market approval by the FDA, was approved by the FDA, and/or was generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

THIRTIETH AFFIRMATIVE DEFENSE

Punitive damages against NPC cannot be recovered based on alleged fraudulent representations to the FDA. *See Buckman Co.* v. *Plaintiffs' Legal Comm.,* 531 U.S. 341, 343 (2001); *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 271-76 (N.J. Super. Ct. App. Div. 2008); *see also* N.J.S.A. § 2A:58C-5(c).

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims, in whole or in part, are barred by the presumption of adequacy, under the New Jersey Products Liability Act, that attaches to drug labeling approved by the Food and Drug Administration, which presumption Plaintiff cannot overcome.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for fraud are barred by Plaintiff's failure to plead them with reasonable particularity as required by Federal Rule of Civil Procedure 9(b) and New Jersey Civil Practice Rule 4:5-8(a).

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or a breach of trust, Plaintiff's claims are barred by Plaintiff's failure to plead them with reasonable particularity as required by New Jersey Civil Practice Rule 4:5-8(a).

THIRTY-FOURTH AFFIRMATIVE DEFENSE

A New Jersey forum is inconvenient to the parties, and this matter should be transferred to its appropriate jurisdiction.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Atlantic County is an improper venue for this case pursuant to New Jersey Civil Practice Rule 4:3-2(3) because NPC was a resident of Morris County at the time of commencement of this action and therefore, if this case is remanded to the Superior Court of New Jersey, it must be transferred to Morris County.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

At the time the product left the control of NPC, it was not defective and there was no practical and technically feasible alternative design without substantially impairing the reasonably anticipated or intended function of the product.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent that plaintiff proves that the product both was capable of and in fact caused the alleged harm, which allegations are denied, plaintiff's claim(s) are barred by N.J.S.A. § 2A:58C-3(a)(3).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims, including the claim for breach of implied warranty, are subsumed and/or barred by the New Jersey Products Liability Act, in whole or in part. *See, e.g.*, N.J.S.A. § 2A:58C-2; *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 54-55, 948 A.2d 587, 589 (2008); *In re Lead Paint Litig.*, 191 N.J. 405, 436-37, 924 A.2d 484, 503-04 (2007); *Brown ex rel. Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 515-18 (D.N.J. 2002).

THIRTY-NINTH AFFIRMATIVE DEFENSE

To the extent that Texas law applies, plaintiff's claims are barred because the warnings that accompanied Elidel® were those approved by the FDA under applicable federal law. *See* Tex. Civ. Prac. & Rem. Code § 82.007.

FORTIETH AFFIRMATIVE DEFENSE

To the extent that Texas law applies: any recovery of punitive or exemplary damages is limited pursuant to Tex. Civ. Prac. & Rem. Code § 41.008; NPC would further show that under the facts of this case, an award of punitive damages consistent with the maximum awards permitted under § 41.008 would be a violation of NPC's state and federal constitutional rights; NPC asserts that Plaintiff's claim for punitive damages is governed and limited by Tex. Civ.

Prac. & Rem. Code §§ 41.001 and 41.003; and NPC hereby pleads and invokes the provisions of same.

FORTY-FIRST AFFIRMATIVE DEFENSE

NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this Answer and its Affirmative Defenses.

WHEREFORE, Defendant Novartis Pharmaceuticals Corporation demands judgment dismissing Plaintiff's Complaint, together with costs and further relief as this Court deems just and proper.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, it is hereby stated that the matter in controversy as against all Defendants is not the subject of any other action pending in any other Court or a pending arbitration proceeding to the best of my knowledge and belief.

Dated: March 11, 2009

Respectfully submitted,

s/ Beth S. Rose
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Attorneys for Novartis Pharmaceuticals Corporation

CERTIFICATE OF SERVICE

I certify that on this 11th day of March 2009, I electronically filed ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION TO THE PLAINTIFF'S COMPLAINT with the Clerk of the Court by using the CM/ECF system, and I caused a true and correct copy of the Answer to be sent via first-class pre-paid mail to the following:

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